

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 1999 list were published in the Federal Register during November 1999.

New Approvals

ANADA Number: 200-233

Pioneer Product: 111-636
Trade Name: Linco Soluble
Ingredients: Lincomycin Hydrochloride
Sponsor: Alpharma, Inc.
Approval Date: September 22, 1999
Status: Over-the-counter
Route: Oral via drinking water
Species: Swine and broiler chickens
Drug Form: Powder
Concentration: 16g lincomycin per 40g packet
Indications: For the treatment and control of swine dysentery (bloody scours) in swine under 250 pounds and for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin in broiler chickens.
Tolerance: 21CFR 556.360: Lincomycin: The ADI for total residues if lincomycin is 25 micrograms per kilogram of body weight per day. A tolerance for residues of lincomycin in **chickens** is not required. A tolerance of 0.6 ppm in liver and 0.1 ppm in muscle are established in **swine**.
Withdrawal: Broiler chickens – zero days
Swine – 6 days

21CFR 520.1263c

NADA Number: 140-908

Trade Name: Veta-Meth[™]
Ingredients: Sulfamethazine
Sponsor: Lloyd, Inc.
Approval Date: September 16, 1999
Status: Over-the-counter
Route: Oral
Species: Beef and nonlactating dairy cattle
Drug Form: Tablet
Concentration: 5, 15, or 25 grams per tablet
Indications: For the treatment of diseases caused by organisms sensitive to sulfamethazine such as bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) caused by *Pasteurella* spp., colibacillosis (bacterial scours) caused by *Escherichia coli*, necrotic pododermatitis (foot rot) caused by *Fusobacterium necrophorum*, calf diphtheria caused by *Fusobacterium necrophorum*, acute mastitis caused by *Streptococcus* spp., acute metritis caused by *Streptococcus* spp. and coccidiosis caused by *Eimeria bovi* or *E. zurni*.
Tolerance: 21CFR 556.670: Sulfamethazine: A tolerance of 0.1 ppm is established for negligible residues in the uncooked edible tissues.
Withdrawal: 10 days

21CFR 520.2260a

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Supplemental Approvals

NADA Number: 141-087

This supplemental application provides for a new indication for the treatment and control of *Gasterophilus nasalis* (3rd instars).

Trade Name: Quest[™] 2% Equine Oral Gel
Ingredients: Moxidectin
Sponsor: Fort Dodge Animal Health Division of American Home Products
Approval Date: October 4, 1999
Status: Over-the-counter
Route: Oral
Species: Horses and ponies
Drug Form: Gel
Concentration: 20 mg per mL
Indications: For the treatment and control of the following stages of gastrointestinal parasites in horses and ponies not used for food:

Large strongyles:

Strongylus vulgaris - (adults and L₄/L₅ arterial stages)
Strongylus edentatus - (adult and tissue stages)
Triodontophorus brevicauda - (adults)
Triodontophorus serratus - (adults)

Small strongyles:

Cyathostomum spp. (adults)
Cylicocyclus spp. (adults)
Cylicostephanus spp. (adults)
Gyalocephalus capitatus - (adults)
Undifferentiated luminal larvae

Encysted cyathostomes:

Late L₃ and L₄ mucosal cyathostome larvae

Ascarids:

Parascaris equorum - (adults and L₄ larval stages)

Pin worms:

Oxyuris equi - (adults and L₄ larval stages)

Hair worms:

Trichostrongylus axei - (adults)

Large-mouth stomach worms:

Habronema muscae - (adults)

Horse stomach bots:

Gasterophilus intestinalis - (2nd and 3rd instars)
Gasterophilus nasalis - (3rd instars)

Patent Number: 4,916,154 Expiration Date: April 10, 2007
Exclusivity: 3 years

21CFR 520.1452

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Suitability Petition Action

Number: 99P-2733/CP1
Sponsor: Wildlife Laboratories, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug, ketamine hydrochloride, which differs from the pioneer product, Vetalar, Fort Dodge Animal Health, Division AHP Corp., NADA 045-290 by the following characteristic: The generic product will provide for a product containing 200 mg/mL ketamine hydrochloride whereas the pioneer product contains 100 mg/mL ketamine hydrochloride.
Action: Denied on November 5, 1999

Number: 99P-0794/CP1
Sponsor: Veterinary Research Associates, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug propofol which differs from the pioneer product, propofol (PropoFlo™), Abbott Laboratories, NADA 141-098, by the following characteristics: Propofol generic differs in concentration, dosage form, and inactive ingredients from the pioneer product.
Action: Filed on March 31, 1999

Number: 99P-0794/CP1
Sponsor: Veterinary Research Associates, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug propofol which differs from the pioneer product, propofol (PropoFlo™), Abbott Laboratories, NADA 141-098, by the following characteristics: Propofol generic differs in concentration, dosage form, and inactive ingredients from the pioneer product.
Action: Denied on November 5, 1999